K08 2326

OCT 0 8 2008

Summary of Safety and Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c)

The assigned 510(k) number is: _____

Applicant Information:

Date Prepared: July 14, 2008

Name: ZONARE Medical Systems, Inc.
420 North Bernardo Ave.
Mountain View, CA 94043

Contact Persons: Linda J. Moore
Director, Regulatory Affairs & Quality Assurance

Telephone Numbers: 650-230-2724

Fax Number: 650-230-2818

Email lmoore@zonare.com

Device Information:

Trade Name: ZONARE z.one *Ultra* Ultrasound System

Device Name: ZONARE Diagnostic Ultrasound System

	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

Marketed Device(s): The ZONARE z.one Ultrasound System (K022858), GE Voluson i(K053435), Philips iU22 (K042540), and Siemens Acuson S2000 (K072786) devices currently in commercial distribution.

Device Description: The z.one Ultra is a general purpose diagnostic ultrasound system. It consists of a portable scanner approximately 8 inches wide and 3 inches high that can be held by the user in one hand and includes buttons for controlling the system and a screen that display ultrasound mages and user interface. The portable scanner can be held by the user in one hand and accommodates a removable transducer module. Signals received from the transducer module are digitized and preprocessed. The transducer module comes into contact with the patient and both transmit and receive ultrasound energy.

The docking station (aka carts) provides holders for the portable scanner, and transducer modules, as well as battery chargers and other accessories. The modification for this submission include new features and functionality that will enhance user convenience and work flow as well as provide clinicians with new indications of use.

Indications For Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal/OB; Abdominal; Intra-operative (abdominal, thoracic, and vascular); Intra-operative Neuro; Pediatric; Small Organ (Thyroid, Breast, Testes, etc.); Neonatal Cephalic; Adult Cephalic; Trans-rectal; Trans-cranial, trans-esoph (cardiac/noncardiac), musculo-skel conventional & superficial, 3D/4D, cardiac adult & pediatric and other applications as shown in section 4.3.

Comparison with Predicate Device: With respect to features and applications, the ZONARE z.one Ultra is comparable and substantially equivalent to the currently marketed ZONARE z.one and the Voluson i, Siemens Acuson S2000, and Philips iU22 in terms of portability, features and functionality. Additionally, they have the same important safety and effectiveness features, as well as design, materials, and construction.

Non-clinical tests: The device has been evaluated according to the applicable medical device safety standards for acoustic output, biocompatibility, cleaning, and disinfection effectiveness as well as thermal, electrical, and mechanical safety.

Clinical Tests: Non Required

Conclusion: ZONARE designs and develops their products according to 21 CFR 820, ISO 13485:2003 quality systems. The device conforms to applicable medical device safety standards and compliance for safety and effectiveness is verified through defined evaluation and market surveillance. Conforming to the required worldwide ultrasound standards, enables ZONARE to state that the ZONARE z.one Ultra Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices current cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2008

Zonare Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K082326
Trade/Device Name: ZONARE System with Doppler & Harmonic Imaging Modes
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: September 20, 2008
Received: September 22, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ZONARE System with Doppler & Harmonic Imaging Modes, as described in your premarket notification:

Transducer Model Number

C5-2 Curvilinear
C6-2 Curvilinear
C9-3 Curvilinear
C8-3r (3D/4D) Curvilinear
P4-1 Phased (Sector) Array
P4-1c Phased (Sector) Array
P10-4 Phased (Sector) Array
E9-4 Endo-Cavity
E9-4 3D Endo-Cavity
L10-5 Linear

L8-3 Linear
L14-5SP Linear
L14-5W Linear
E14-5 EndoScopic
P8-3T Tran-Esophageal
AUX CW2
AUX CW4
AUX CW5

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

for Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

4.3 Indications for use

This device is intended for use by a qualified physician for ultrasound evaluation of the following: Fetal, Abdominal, Intraoperative, Pediatric, Small organ/parts (breast/testes, thyroid, etc), Transvaginal, Transrectal, Transcranial, Trans-esoph, Trans-urethral, OB/GYM, Cardiac, Pelvic, Neonatal/Adult cephalic. Vascular, 3D/4D, Tissue elasticity, Musculoskeletal (cardiac, Superficial Musculoskeletal, and Peripheral Vascular applications.

Diagnostic Ultrasound Indication for Use

System: ZONARE System with Doppler & Harmonic Imaging Modes

Transducer: ZONARE System (Union of all Transducer Types)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific	B[1]	M	PWD[2]	CWD *CWD Aux*	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic							
General Application	Fetal	P	P	P	P	P	P	P[5]
	Abdominal	P	P	P	P	P	P	P[5]
	Intra-operative (Specify)[6]	P	P	P		P	P	P[5]
	Intra-operative (Neuro)	P		P		P	P	P[5]
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P[5]
	Pediatric Aux				*N*			
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P[5] N[8]
	Neonatal Cephalic	P	P	P	P	P	P	P[5]
	Adult Cephalic	P	P	P	P	P	P	P[5]
	Trans-rectal	P	P	P		P	P	P[5]
	Trans-vaginal	P	P	P		P	P	P[5]
	Trans-urethral							
	Trans-esoph. (non-Card.)	N	N	N	N	N	N	N[5]
	Musculo-skel. (Conventional)	N	N	N		N	N	N[5, 8]
	Musculo-skel. (Superficial)	N	N	N		N	N	N[5, 8]
	Intra-luminal							
	Other (Specify) (3D/4D)	N	N	N		N	N	
Cardiac	Cardiac Adult	P	P	P	P	P	P	P[5]
	Cardia Adult Aux				*N*			
	Cardiac Pediatric	P	P	P	P	P	P	P[5]
	Cardiac Pediatric Aux				*N*			
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N[5]
	Other (Specify) (3D/4D)	N	N	N	N	N	N	
Peripheral vascular	Peripheral Vessel	P	P	P	N	P	P	P[5] N[8]
	Peripheral Vessel Aux				*N*			
	Other (Specify) (3D/4D)	N	N	N		N	N	

N = new indication; P = previously cleared by FDA 510k # 022858)
[1] Includes B-Mode and Harmonic imaging (HI)
[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)
[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)
[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)
[5] Color M-Mode (CM)
[6] Abdominal includes renal, GYN/Pelvic
[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)
[8] Freehand tissue elasticity

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: Curvilinear Transducers C5-2*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General applications	Fetal	P	P	P		P	P	P[5]
	Abdominal[6]	P	P	P		P	P	P[5]
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P[5]
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510k # 022858 E added under Appendix E *market designation

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: Curvilinear Transducers C6-2*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General applications	Fetal	P	P	P		P	P	P[5]
	Abdominal[6]	P	P	P		P	P	P[5]
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P[5]
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510k # 022858 E= added under Appendix E *market designation

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: Curvilinear Transducers C9-3*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General applications	Fetal	E	E	E		E	E	E[5]
	Abdominal[6]	E	E	E		E	E	E[5]
	Intra-operative (Abdominal)	N	N	N	N	N	N	N[5]
	Intra-operative (Vascular)	N	N	N	N	N	N	N[5]
	Laparoscopic							
	Pediatric	E	E	E		E	E	E[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N	N	N	N	N	N[5]
	Musculo-skel. (Superficial)	N	N	N	N	N	N	N[5]
	Intra-luminal							
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	E	E	E		E	E	E[5]
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510k # 022858 E= added under Appendix E *market designation,

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: Curvilinear Transducers C8-3r* (3D/4D)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General applications	Fetal	N	N	N		N	N	N[5]
	Abdominal[6]	N	N	N		N	N	N[5]
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)	N	N	N		N	N	N[5]
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	N	N	N		N	N	N[5]
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510k # 022858 E= added under Appendix E *market designation

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: Phased (Sector) Array Transducers P4-1*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P	P	P	P	P[5]
	Abdominal[6]	P	P	P	P	P	P	P[5]
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P	P	P	P	P[5]
	Adult Cephalic/ trans cranial	P	P	P	P	P	P	P[5]
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P[5]
	Cardiac Pediatric	P	P	P	P	P	P	P[5]
	Trans-esoph. (Cardiac)							
	Other (Specify) (3D/4D)							
Peripheral vascular	Peripheral Vascular	P	P	P	P	P	P	P[5]
	Other (Specify)							

N = new indication; P=previously cleared by the FDA510k # 022858 E= added under Appendix E *market designation

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: Phased (Sector) Array Transducers P4-1c*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5], [8]
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P	P	P	P	P[5]
	Abdominal[6]	P	P	P	P	P	P	P[5]
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P	P	P	P	P[5]
	Adult Cephalic/ trans cranial	P	P	P	P	P	P	P[5]
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P[5]
	Cardiac Pediatric	P	P	P	P	P	P	P[5]
	Trans-esoph. (Cardiac)							
	Other (Specify) (3D/4D)							
Peripheral vascular	Peripheral Vascular	P	P	P	P	P	P	P[5]
	Other (Specify)							

N = new indication; P=previously cleared by the FDA510k # 022858 E= added under Appendix E *market designation

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: Phased (Sector) Array Transducers P10-4

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[7,8]
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P	P	P	P	P[5]
	Abdominal[6]	P	P	P	P	P	P	P[5]
	Intra-operative (Specify)[7]	N	N	N		N	N	N[5]
	Intra-operative (Neuro)	N	N	N		N	N	N[5]
	Laparoscopic							
	Pediatric	P	P	P	P	P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	P	P	P	P	P	P	P[5]
	Adult Cephalic/ trans cranial	P	P	P	P	P	P	P[5]
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P	P	P	P	P	P	P[5]
	Cardiac Pediatric	P	P	P	P	P	P	P[5]
	Trans-esoph. (Cardiac)							
	Other (Specify) (3D/4D)							
Peripheral vascular	Peripheral Vascular	P	P	P	P	P	P	P[5]
	Other (Specify)							

N = new indication; P=previously cleared by the FDA510k # 022858 E= added under Appendix E *market designation

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: Endo-Cavity Transducers E9-4*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P		P	P	P[5]
	Abdominal							
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P[5]
	Trans-vaginal	P	P	P		P	P	P[5]
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510k # 022858 E = added under Appendix E *market designation E9-4,

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: Endo-Cavity Transducers* E9-4 3D

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,6,8]
Ophthalmic	Ophthalmic							
General application	Fetal	N	N	N		N	N	N[5]
	Abdominal							
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	N[5]
	Trans-vaginal	N	N	N		N	N	N[5]
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)	N	N	N		N	N	N[5]
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510k # 022858 E= added under Appendix E *market designation

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: Linear Transducers L10-5

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General application	Fetal	P	P	P		P	P	P[5]
	Abdominal[6]	P	P	P		P	P	P[5]
	Intra-operative (Specify)[7]	P	P	P		P	P	P[5]
	Intra-operative (Neuro)	P		P		P	P	P[5]
	Laparoscopic							
	Pediatric	P	P	P		P	P	P[5]
	Small Organ (Thyroid, Breast, Testes, etc.)	P	P	P		P	P	P[5] N[8]
	Neonatal Cephalic	P	P	P		P	P	P[5]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N	N		N	N	N[5, 8]
	Musculo-skel. (Superficial)	N	N	N		N	N	N[5, 8]
	Intra-luminal							
	Other (Specify)[8] (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	P	P	P		P	P	P[5] N[8]
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510k # 022858 E=added under Appendix E *market designation L10-5,

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: Linear Transducers L8-3*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic							
General application	Fetal	E	E	E		E	E	E[5]
	Abdominal[6]	E	E	E		E	P	E[5]
	Intra-operative (Specify)[7]	E	E	E		E	E	E[5]
	Intra-operative (Neuro)	E		E		E	E	E[5]
	Laparoscopic							
	Pediatric	E	E	E		E	E	E[5]
	Small Organ (Thyroid, Breast, Testes, etc.)	E	E	E		E	E	E[5] N[8]
	Neonatal Cephalic	E	E	E		E	E	E[5]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N	N		N	N	N[5, 8]
	Musculo-skel. (Superficial)	N	N	N		N	N	N[5, 8]
	Intra-luminal							
	Other (Specify)[8] 3D/4D							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	E	E	E		E	E	E[5] N[8]
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510k # 022858 E= added under Appendix E *market designation

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Examples may include A-mode, Amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue Motion Doppler, Color velocity imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: Linear Transducers L14-5SP*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic							
General application	Fetal	E	E	E		E	E	E[5]
	Abdominal[6]	E	E	E		E	E	E[5]
	Intra-operative (Specify)[7]	E	E	E		E	E	E[5]
	Intra-operative (Neuro)	E		E		E	E	E[5]
	Laparoscopic							
	Pediatric	E	E	E		E	E	E[5]
	Small Organ (Thyroid, Breast, Testes, etc.)	E	E	E		E	E	E[5] N[8]
	Neonatal Cephalic	E	E	E		E	E	E[5]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N	N		N	N	N[5, 8]
	Musculo-skel. (Superficial)	N	N	N		N	N	N[5, 8]
	Intra-luminal							
	Other (Specify)[8] 3D/4D							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	E	E	E		E	E	E[5] N[8]
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510k # 022858 E= added under Appendix E *market designation

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Examples may include A-mode, Amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue Motion Doppler, Color velocity imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: Linear Transducers L14-5W*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5, 8]
Ophthalmic	Ophthalmic							
General application	Fetal	E	E	E		E	E	E[5]
	Abdominal[6]	E	E	E		E	E	E[5]
	Intra-operative (Specify)[7]	E	E	E		E	E	E[5]
	Intra-operative (Neuro)	E		E		E	E	E[5]
	Laparoscopic							
	Pediatric	E	E	E		E	E	E[5]
	Small Organ (Thyroid, Breast, Testes, etc.)	E	E	E		E	E	E[5] N[8]
	Neonatal Cephalic	E	E	E		E	E	E[5]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)	N	N	N		N	N	N[5, 8]
	Musculo-skel. (Superficial)	N	N	N		N	N	N[5, 8]
	Intra-luminal							
	Other (Specify)[9] 3D/4D							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vascular	Peripheral Vascular	E	E	E		E	E	E[5] N[8]
	Other (Specify) 3D/4D							

N = new indication; P=previously cleared by the FDA 510k # 022858 E=added under Appendix E *market designation

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

Examples may include A-mode, Amplitude Doppler, 3-D imaging, Harmonic imaging, Tissue Motion Doppler, Color velocity imaging

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: EndoScopic Transducer Array E14-5*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General applications	Fetal							
	Abdominal							
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	N[5]
	Trans-vaginal	N	N	N		N	N	N[5]
	Trans-urethral							
	Trans-esoph. (non-Card.)	N	N	N		N	N	N[5]
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510k # 022858 *market designation E14-5

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: Tran-Esophageal P8-3T*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General applications	Fetal							
	Abdominal							
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)	N	N	N	N	N	N	N[5]
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	N	N	N	N	N	N	N[5]
	Other (Specify)							
Peripheral Vessel	Peripheral Vessel							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510k # 022858 *market designation (TEE)

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: AUX CW2* (Common name pencil probe)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General application	Fetal							
	Abdominal							
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric				*N*			
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult				*N*			
	Cardiac Pediatric				*N*			
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510k # 022858 *market designation

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: AUX CW4* (Common name pencil probe)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,6,8]
Ophthalmic	Ophthalmic							
General application	Fetal							
	Abdominal							
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric				*N*			
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral vascular	Peripheral vascular				*N*			
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510k # 022858 *market designation

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number K082326

System: ZONARE System with Doppler and Harmonic imaging modes

Transducer: AUX CW5* (Common name Pencil Probe)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Track I & III)	B[1]	M	PWD[2]	CWD	Color Doppler[3]	Combined Modes[4]	Other[5,8]
Ophthalmic	Ophthalmic							
General application	Fetal							
	Abdominal							
	Intra-operative (Specify)[7]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric				*N*			
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other (Specify) (3D/4D)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral vascular	Peripheral vascular				*N*			
	Other (Specify)							

N = new indication; P=previously cleared by FDA 510k # 022858 *market designation CW 2, CW4, CW5

[1] Includes B-Mode and Harmonic imaging (HI)

[2] Includes PWD-Mode imaging and High Pulse Repetition Rate PWD-Mode (HPRF)

[3] Includes Color Doppler (CD), Directional Power Doppler (DPD), and Power Doppler (PD)

[4] Includes B+M, B+M+CM, M+CM, B+CD+M+CM, B+CD+PWD where CD could represent (CD, DPD, PD, or BD)

[5] Color M-Mode (CM)

[6] Abdominal includes renal, GYN/Pelvic

[7] Intra operative include abdominal, thoracic (cardiac) and vascular (PV)

[8] Freehand tissue elasticity

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